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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/444,095	11/22/1999	SOFI M. IBRAHIM	ARMY-123	8187

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EXAMINER

SISSON, BRADLEY L

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 04/01/2002

72

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/444,095

Applicant(s)

IBRAHIM, SOFI M.

Examiner

Bradley Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-35,38,39 and 63-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-35,38,39 and 63-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 08 May 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/444,095 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 31-35, 38, 39, and 63-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. See pages 2-5 of the Office action of 07 November 2000 for the basis of the rejection.

Response to argument

4. At page 2-3 of the response received 10 January 2002 requests that the examiner direct attention to where the invention of claims 31-35 are somehow directed to the binding of proteins. As stated therein: "Claims 31-35, 38-39, and 63-67 do not include any reference to protein binding or amplification."

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5. In support of the prior interpretation of claims wherein they are considered to encompass protein binding and nucleic acid amplification, attention is first directed to claim 38 which states: the "sample collection assembly is coated with a material that binds non-specifically with nucleic acids or proteins." In view of the claims explicitly reciting the capacity for DNA or RNA to be removed from cells, and that cells unquestionably comprise proteins, and that the very element used to bind nucleic acids also binds protein with equal affinity, it stands to reason that the claimed method will also result in the purification of proteins. It is further noted that at page 4, last paragraph, applicant defines their invention as "an apparatus for purifying DNA, RNA, proteins (antigens and antibodies) or cells and is adaptable for detection of such moieties by a variety of detection formats with a wide range of applications in the medical diagnostics, counter terrorism and the health care arena."

6. As for the claims encompassing amplification reactions, it is noted that the claims use the term "comprises" in defining the method steps. The term "comprises" allows for the inclusion of additional method steps, which, in the present case, could be that of nucleic acid amplification. As reproduced above, applicant states in the specification that the apparatus can be readily adapted so as to allow for a "wide range of [detection] applications in the medical field. Certainly, the use of an amplification reaction for the detection target sequences meets this limitation. While agreement is reached in that the claims do not positively recite performing such method steps, the Office is to interpret the claims as broadly as is reasonably possible. In view of how applicant has characterized their invention, the interpretation applied by the Office is reasonable.

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7. At page 3 of the response it is asserted, "claims 31-35, 38 and 39 describe a device and a method for non-specific binding of nucleic acids." This assertion has been carefully considered and has not been found persuasive, as the claims do not recite that they are drawn to a method of "non-specific binding of nucleic acids." Rather, and using claim 31 as an example, begins by stating that the claim is drawn to a "[m]ethod of DNA or RNA purification" not "non-specific binding." In short, applicant is arguing limitations not present in the claims. Applicant is reminded that the Office is to interpret the claims as broadly as is reasonably possible. If applicant wishes to claim a method whereby nucleic acids are bound in a non-specific manner, they are invited to consider amending the claims accordingly.

8. Applicants request clarification at page 4 of their response as to how the claim can be interpreted as encompassing amplification prior to removal of the nucleic acids from a denaturing solution.

9. In response to this request it is noted that the claims do not positively recite when or where any amplification step is to occur. Accordingly, and in the absence of evidence to the contrary, the claims fairly encompassing such a step prior to as well as subsequent to the removal of nucleic acid sequences from the denaturing solution. It stands to reason that when one is using minute quantities of cells that the nucleic acid being removed from the cell be increased in quantity, e.g., amplified, so that losses incurred through binding and precipitation be minimized. Upon review of the specification it is noted that the wand may have a binding member bound thereto which can be oligonucleotides (see page 7, penultimate paragraph). The use of low stringency conditions could well satisfy the requirement for "non-specific binding."

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10. While applicant presents statements that "PCR amplification is not the subject of claims 31-35, 38-39 or 63-67" (response at page 4, last sentence), the claims encompass just such embodiments. If applicant wishes for their claims to not encompass these alternative embodiments, applicant is invited to amend the claims so that they are more in line with their intentions.

11. Agreement is reached where at page 6 of the response argument is presented that references presented as being state of the art should be considered as such sans evidence to the contrary. Applicant is advised, however, that whether the art is presented for simply historical perspective, or as indicative of the state of the art at the time of filing, none of the cited documents have been considered on the merits unless provided by applicant and cited on an Information Disclosure Statement.

12. At page 7 of the response it is asserted that "Claims 31-35, 38-39, and 63-65 contain a sufficient description of the invention, and of the steps involved in using the invention to enable one skilled in the art to make and use the invention for isolating nucleic acids." This argument has been fully considered and has not been found persuasive, as the claims in and of themselves do not rise to the level of disclosure so as to be fully enabling. Truly, if such were the case then there would be no need for a specification.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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14. Claims 31-35, 38-39 and 63-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. The term "deep" in claims 66 and 67 is a relative term, which renders the claim indefinite. The term "deep" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Claims 66 and 67 depend from independent claims 63 and 31, respectively. Said claims 31 and 63 are similarly rejected, as are claims that depend therefrom as they fail to overcome this issue.

Response to argument

16. At page 8 of the response applicant states that "deep reactive etching" is a term of art and is well known and as such the claims are not indefinite. This argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection as applicant's argument is conclusory and void of any factual or evidentiary underpinning.

17. Claims 31-35, 38-39, and 63-67 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. See the Office action of 07 November 2000 for the basis of the rejection.

Response to argument

18. At pages 8-9 of the response argument is presented that the claims do not require any amendments, as they do not positively recite performing hybridization reactions. This argument has been fully considered and has not been found persuasive as the claims have sufficient

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breadth of scope so to encompass just such a methodology and a cursory review of the disclosure finds that applicant indeed contemplates just such an embodiment. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained. Applicant is encouraged to consider amending the claims so that they positively exclude performing hybridization reactions with sequence-specific probes.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 3-35, 38-39, and 63-67 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ji et al., in view of Henco et al., Piaso et al., Lockhart et al., Tuunanen (WO 94/18564).

22. See pages 8-11 of the Office action of 07 November 2000 for the basis of the rejection.

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Response to argument

23. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

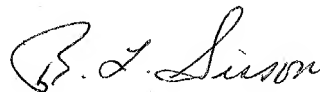
Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is 703-308-3978.

The examiner can normally be reached on Monday through Thursday from 6:30 AM to 5 PM.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

26. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

bls
March 24, 2002